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TITLE: Physiological Stress Reactivity and Breast Cancer

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NOTE:

This project was originally approved and funded for a three-year period from October 1, 1999 till September 30, 2002. The project's Principal Investigator, Pathik D. Wadhwa, M.D., Ph.D., left the University of Kentucky College of Medicine (applicant organization) to accept a new faculty position at the University of California, Irvine, College of Medicine from September 1, 2000 onwards. The University of Kentucky formally relinquished the grant award and it was transferred to the University of California, Irvine. The terms of the grant were changed from 1 Oct 1999 – 30 Oct 2002 to 1 Oct 1999 – 30 Oct 2004, with no activity and monies authorized for expenditure between 23 Aug 2002 and 15 June 2002. Thus, this report covers work performed at the University of California, Irvine, for only the two and a half month period from 16 June 2002 till 31 Aug 2002.

INTRODUCTION:

The broad objective of the present program of research is to study physiological processes that may mediate the links between psychological states and cancer. Specifically, the present study is designed to conduct an investigation of the cross-sectional associations between indices of stress reactivity and psychological coping styles in women with breast cancer and matched healthy controls. The aims of the project are: (1) To quantify parameters of biological reactivity to a behavioral stress paradigm in women with and without breast cancer; (2) To examine (a) group differences between women with and without breast cancer in biological stress reactivity, and (b) the effects of menopause and familial risk on biological stress reactivity and emotional expression; and (3) To develop the methodology and obtain preliminary data which could justify subsequent, prospective research with high-risk populations.

BODY:

Since moving to the University of California, Irvine, the PI has now completed all the following steps and has resume this research study. These steps include:

1. Setting up a behavioral medicine research laboratory
2. Obtaining IRB approval for the project from the University of California, Irvine
3. Obtaining approval from the University's General Clinical Research Center (GCRC) to conduct the study at the GCRC.
4. Obtaining the necessary documentation for the UCI Certificate of Environmental Compliance (Appendix 4), IRB approval (Appendix 5), and Safety program Plan (Appendix 7).
5. Obtaining approval from the University's Oncology Practice to screen and recruit research subjects for the study.
6. Setting up a collaboration with an oncologist (Dr. Rita Mehta) and biochemist (Dr. Aleksandra Chicz-DeMet) for conducting the clinical and physiological components of the study.
7. Recruiting the necessary staff (graduate research assistant, laboratory assistant) to conduct the study.

In accordance with the revised **statement of work**, the following have been completed:

- a. *Recruitment and assessment*: Three new subjects (all in the breast cancer group) have been recruited and assessed.
- b. *Database*: The relational database, comprising of three categories of data -- clinical, sociodemographic + psychosocial, and physiological -- has been constructed and is in place.
- c. *Biosamples* have been collected and frozen at -70 degrees C in the PI's laboratory at the University of California, Irvine.

KEY RESEARCH ACCOMPLISHMENTS:

The study protocol has been set up successfully at UC Irvine and data collection is on-going. The first preliminary analyses are scheduled to be performed in June 2003. Hence, there are no specific accomplishments to report at this stage of the project.

REPORTABLE OUTCOMES:

As mentioned earlier, data collection is on-going, and there are no reportable outcomes at this stage of the project.

CONCLUSIONS:

The project has successfully been transferred to the University of California, Irvine. There have been no problems associated with the implementation of this project so far at the new site.

REFERENCES: none

APPENDICES: none